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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,857	10/25/2001	Mark G. Erlander	485772002900	1235

7590 05/21/2003
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EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

12

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,857

Applicant(s)

ERLANDER ET AL.

Examiner

Shar Hashemi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Applicant's Response (filed 07 February 2003) was received and entered as Paper No. 9. The claims pending in this application are **Claim(s) 1-32**. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Response to Arguments

2. Applicant's state the following: 1. Lin et al do not teach the use of "random primers" to anneal to a first strand cDNA to synthesize a complementary second cDNA strand as required by the instant claims. 2. Lin et al disclose "mRNA fragments that are contacted with primers to permit the production of mRNA/cDNA hybrids in step (e) of claim 1." 3. Lin et al do not teach the poly(dT) primer is linked to a promoter. 4. The promoter-linked primer of the instant invention is complementary to the antisense of the starting template instead of being complementary to the starting template. Applicant's arguments have been fully considered but they are not persuasive. The Applicant is directed to the rejections set forth below.

Sequence Rules

3. This application does comply with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 10/01/02 was received and entered. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al (US 2002/0137709 A1 September 26, 2002) in view of Adams et al (US 6,297,365 B1 October 2, 2001).

Lin et al teach a method of amplifying RNA sequences complementary to one or more than one target polynucleotide that is single stranded or made single stranded (page 12, claim 1). They teach forming double stranded cDNA templates containing sequences present in a target polynucleotide, wherein the sequences are operably linked to a promoter region by annealing the single stranded target polynucleotide with a first oligonucleotide comprising a primer operably linked to a promoter region to form a first complex (pg. 12, claim 1, step a), synthesizing a first strand cDNA by reverse transcription of the first complex (pg. 12, claim 1, step b), annealing the

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first strand cDNA, after denaturing the mRNA/cDNA hybrid or degrading the RNA from the hybrid, with a plurality of second oligonucleotides comprising a random primer region to form a population of second complexes (pg. 12, claim 1, step e), forming double stranded cDNA templates from the population of second complexes with DNA polymerase activity (pg. 13, claim 5), transcribing the cDNA templates with an RNA polymerase capable of initiating transcription via the promoter region to produce amplified RNA containing sequences complementary to the target polynucleotide (pg. 13, claim 6). They teach the target polynucleotide is mRNA (pg. 12, claim 1). They teach more than one target polynucleotide are a cellular mRNA preparation (see Example 3, page 9). They teach the first oligonucleotide comprises a primer containing a poly dT sequence (pg. 13, claim 14). They teach the poly dT sequence is at least about eight dT in length (pg. 3, par. 37). They teach the random primer region comprises at least about six random nucleotides or at least about nine random nucleotides (pg. 3, par. 38). They teach DNA polymerase activity is DNA dependent (pg. 13, claim 6). They claim the DNA dependent polymerase activity is Taq polymerase (pg. 13, claim 6). They teach where the above annealing, synthesizing, annealing, forming and transcribing components of the method are repeated to further amplify the RNA sequences complementary to one or more than one target polynucleotide (pg. 12, claim 2). They teach the oligonucleotide comprises a known primer sequence that is complementary to the 3' region of the aRNA (pg. 13, claim 13). They teach the first oligonucleotide comprise a T7 promoter region (pg. 13, claim 11). They teach the third oligonucleotide comprises a T3 or SP6 promoter region (pg. 13, claim 11).

Lin et al do not teach exonuclease activity and exonuclease deficient Klenow.

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Adams et al teach exonuclease activity and exonuclease deficient Klenow (col. 16, line 24). They teach amplification procedures using exonuclease deficient Klenow and Taq polymerase (col. 16, lines 16-30).

One of ordinary skill at the time the invention was made would have been motivated to apply Adams et al's exonuclease deficient Klenow to Lin et al's method of amplifying RNA sequences to create conditions compatible with RNA transcript production (col. 7, lines 35-50). It would have been prima facie obvious to apply Adams et al's exonuclease deficient Klenow to Lin et al's method of amplifying RNA sequences to create conditions compatible with RNA transcript production.

7. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon (US 6,132,997 October 17, 2000) in view of Adams et al (US 6,297,365 B1 October 2, 2001).

Shannon discloses a method of amplifying RNA sequences complementary to one or more than one target polynucleotide that is single stranded or made single stranded comprising the limitations set forth in claims 1-32 (see whole document, especially col. 3, lines 20-34; col. 4, lines 12-63; col. 5, lines 35-67; col. 27-67; col. 7, lines 21-67; col. 8, lines 25-67; col. 9, see example 1).

Shannon does not teach exonuclease activity and exonuclease deficient Klenow.

Adams et al teach exonuclease activity and exonuclease deficient Klenow (col. 16, line 24). They teach amplification procedures using exonuclease deficient Klenow and Taq polymerase (col. 16, lines 16-30).

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One of ordinary skill at the time the invention was made would have been motivated to apply Adams et al's exonuclease deficient Klenow to Shannon's method of amplifying RNA sequences to create conditions compatible with RNA transcript production (col. 7, lines 35-50). It would have been prima facie obvious to apply Adams et al's exonuclease deficient Klenow to Shannon's method of amplifying RNA sequences to create conditions compatible with RNA transcript production.

8. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al (US 2003/0022318 A1 January 30, 2003) in view of Adams et al (US 6,297,365 B1 October 2, 2001).

Lin et al teach a method of amplifying RNA sequences complementary to one or more than one target polynucleotide that is single stranded or made single stranded comprising the limitations set forth in claims 1-32 (see whole document, especially col. 3, par. 37-44; page 4, par. 54; page 4, par. 57; page 6, par. 81; page 7, par. 91-98; page 10, par. 120-122; page 13, par. 138-145).

Lin et al do not teach exonuclease activity and exonuclease deficient Klenow.

Adams et al teach exonuclease activity and exonuclease deficient Klenow (col. 16, line 24). They teach amplification procedures using exonuclease deficient Klenow and Taq polymerase (col. 16, lines 16-30).

One of ordinary skill at the time the invention was made would have been motivated to apply Adams et al's exonuclease deficient Klenow to Lin et al's method of amplifying RNA sequences to create conditions compatible with RNA transcript production (col. 7, lines 35-50). It would have been prima facie obvious to apply Adams et al's exonuclease deficient Klenow to

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Lin et al's method of amplifying RNA sequences to create conditions compatible with RNA transcript production.

CONCLUSION

9. Claims **1-32** are rejected for the reasons set forth above.

10. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal. If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice

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of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840. The examiner can normally be reached Monday-Friday from 8:00AM – 5:00PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

The fax number for this examiner is (703) 746-9038. Before faxing any papers, please inform the examiner to avoid lost papers. Please note the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, Tracey Johnson, whose telephone number is (703) 305-2982.

Examiner Hashemi



Ethan Whisenant, Ph.D.
Primary Examiner
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